

DOCKET NO.: PHRM0027-101/00159.US1
SERIAL NO.: 09/738,022

PATENT
FILED: December 15, 2000

REMARKS

Claims 1-6 and 18-20 were pending. Claims 18-20 have been withdrawn from consideration as directed to an non-elected invention. Claims 1-6 and 18 have been amended. New claims 27-35 have been added.

Claim 1 has been amended to further clarify the preamble. Claims 2-6 have been amended so as to conform to claim 1, as amended. Claim 18, withdrawn from consideration, has been to further clarify the preamble.

New claims 27-35 are similar to originally filed claims 1-6 and 18-20.

The Abstract has been amended.

No new matter has been added.

Restriction Requirement

Applicants point out that the Restriction Requirement mailed January 15, 2003, required election of product claims (Group I; claims 1-6) or process claims (Group IV; claims 18-20) under 35 U.S.C. 121. Applicants elected the product claims in response to the Restriction Requirement. The process claims include all the limitations of the product claims. In the event that the product claims are found to be allowable, Applicants respectfully request rejoinder of the process claims (withdrawn claims 18-20) as well as new claims 33-35), as directed by MPEP §821.04.

Objection to the Abstract

The Abstract of the Disclosure was objected to "because there is no structural makeup depicted for instant elected invention." Applicants have amended the Abstract to include the claimed structure and accordingly request withdrawal of the Objection.

Rejection under 35 U.S.C. 112, second paragraph

Claims 1-6 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Office notes that the term "comprising" is "open-ended and thus implies more than what is positively recited."

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Applicants have amended the claims to recite "A composition comprising a compound of formula ...". Applicants believe that this amendment clarifies the claims and overcomes the rejection under U.S.C. §112, second paragraph. Applicants do not expect the scope of the claims to be narrowed by the amendments to claims 1-6.

Applicants respectfully request withdrawal of the rejection under 35 U.S.C. 112, second paragraph.

Rejection under 35 U.S.C. 112, first paragraph

Claims 1 and 2 were rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to teach how to make the claimed invention. Applicants do not agree.

"A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)." (M.P.E.P. § 2163). The M.P.E.P. also states that:

Proof of enablement will be required for other members of the claimed genus *only* where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.

(M.P.E.P. § 2163, emphasis added).

Although the Office acknowledges that the specification is "enabling for the preparation of non-radiolabelled compounds as well as tritium, ³⁵S and ¹²⁵I", the Office alleges that the specification does not "provide enablement for all remaining isotopic forms." (Office Action, page 3). The Office further alleges that there "are no starting material sources or reaction schemes enabling the preparation of other isotopic forms such as O, N or C that can be present in rings and in chains within the instant formula." *Id.*

The Office, however, has failed to provide any evidence demonstrating that one of skill in the art would not be able to make the claimed invention or need to practice undue experimentation. The Office, save its conclusory statements, has failed to provide any sound scientific reasoning why the art-skilled could not make the radiolabeled compounds within the scope of claim 1. Conclusory statements are insufficient to support an allegation that claims are not enabled. Accordingly, without such evidence the rejection should be withdrawn.

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If the Office maintains the enablement rejection with only written allegations that appear to be based solely on the knowledge of the Examiner, Applicants respectfully request that the Examiner submit an affidavit as to why the present application is not enabled in view of the absence of other scientific evidence (*i.e.* scientific publications).

The art-skilled would readily be able to make and use the compounds within the scope of the pending claims, including compounds including isotropic forms other than tritium, ³⁵S and ¹²⁵I. Substituting isotropic forms for non-isotropic forms is routinely performed by the art-skilled and does not constitute undue experimentation. Requiring Applicants to include synthetic schemes for "preparation of other isotopic forms such as O, N or C that can be present in rings and in chains within the instant formula" is in stark contrast to the well-settled law that the specification need not disclose what is well known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Applicants have provided at least one method for making the claimed invention that "bears a reasonable correlation to the entire scope of the claim". The Office has failed to provide any "adequate reasons" as to why a person skilled in the art could not make the genus as a whole without undue experimentation. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. 112, first paragraph.

Objection to the Claims

Claims 3-6 are objected to as being dependant upon a rejected base claim. The Office notes that claims 3-6 would be allowable if "rewritten in independent form including all of the limitations of the base claim and any intervening claims." Applicants believe that the claim amendments and argument set forth above overcome the rejections of the base claim. Notwithstanding, Applicants may rewrite claims 3-6 as independent claims in a future response should Applicants' arguments and amendments be unavailing.

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Conclusion

Applicants believe the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 665-6904 to clarify any unresolved issues raised by this response.

Respectfully submitted,



Gwilym John Owen Attwell
Registration No. 45,449

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COZEN O'CONNOR
1900 Market Street
Philadelphia, PA 19103-3508
Telephone: (215) 665-6904
Facsimile: (215) 701-2004